

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CAREDX, INC.)	
)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 19-662 (CFC)
)	
NATERA, INC.,)	JURY TRIAL DEMANDED
)	
Defendant.)	

CAREDX’S OPPOSITION TO NATERA’S MOTION TO DISMISS

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I. NATURE AND STAGE OF THE PROCEEDINGS

On April 10, 2019, Plaintiff CareDx, Inc. (“CareDx”) filed its Complaint alleging that Defendant Natera, Inc. (“Natera”) is making false, misleading and disparaging statements that Natera’s “me too” product is superior to CareDx’s patented kidney transplant surveillance diagnostic test, in violation of the federal Lanham Act 15 U.S.C. 1125(a) and the common law of unfair competition. On May 31, 2019, Natera moved to dismiss the Complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) and 12(b)(6). CareDx opposes the motion. Additionally, CareDx respectfully requests that the Court set a scheduling conference while this motion is pending to avoid Natera achieving an unwarranted delay of this action.

II. SUMMARY OF THE ARGUMENT

As CareDx explained in its detailed Complaint, Natera has begun a dangerous false advertising campaign to deceive doctors, healthcare professionals, insurance companies and patients about the emerging market for advanced organ transplant surveillance tests. Natera is attempting to persuade the public that Natera’s “me too” test (Prospera) is supposedly superior to CareDx’s AlloSure to harm CareDx through lost sales, loss of goodwill, and injury to its reputation. Primarily, Natera contends that its false advertising to doctors and patients about cutting-edge medical tests is immune to legal action because Prospera is not yet on the market. This defies not only logic, but, thankfully, the law. The Lanham Act protects a competitor who “believes that he or she is *or is likely to be* damaged” by defendant’s act. 15 U.S.C. § 1125(a)(1)(B) (emphasis added).

First, CareDx has standing to bring this suit. Natera is a direct competitor of CareDx, and Natera is issuing press releases and distributing marketing materials at conferences that explicitly and falsely compare the efficacy and sensitivity of its Prospera test to CareDx’s AlloSure test. Surely, CareDx has plausibly alleged that “it is likely to be damaged” by Natera’s

false claims that CareDx's test is inferior, which harm CareDx's ability to sell its AlloSure test. This is a classic false advertising case and Natera should not be able to escape the consequences of its deceitful misbehavior by arguing that it has not yet successfully made a sale.

Second, CareDx has met the requirements to allege a Lanham Act false advertising claim. The Complaint alleges that Natera made false statements that Prospera is superior to AlloSure. These false advertisements go to the very heart of the efficacy of CareDx's test. It is unquestionably plausible—and even obvious—that such misleading comparisons and put-downs of CareDx's product will affect the purchasing decisions of healthcare providers, patients and insurance companies and cause harm to CareDx's reputation and sales efforts.

Contrary to Natera's mischaracterization of its false statements as mere "scientific disagreement," Natera's false advertisements go way beyond statements in a scientific article. Natera instead takes the results of its fatally-flawed Natera Study, deceptively compares them to the results of CareDx's robust clinical trial, and falsely asserts that Prospera is superior to AlloSure. This is actionable wrongdoing.

Third, CareDx has met the requirements to allege trade disparagement and state law unfair competition. Natera has disparaged CareDx's AlloSure test through its misrepresentations in the relevant market. As demonstrated below, CareDx has pled plausible facts sufficient to establish a claim for unfair competition under Delaware common law and, when (as required on a motion to dismiss) they are viewed in the light most reasonable to CareDx, are more than sufficient to state a claim for relief. Natera also argues that CareDx fails to identify what portions of the Delaware Unfair or Deceptive Trade Practices Act have been violated. Untrue, as explained below.

Natera's motion to dismiss should be denied.

III. STATEMENT OF FACTS

CareDx’s revolutionary AlloSure product is a patented kidney transplant surveillance diagnostic test. D.I. 1 ¶1. It is clinically and analytically validated and Medicare-covered. *Id.* ¶2. AlloSure is a non-invasive blood test that is a game-changer because it can ensure that healthcare professionals get the critical and reliable information necessary to manage patients – information that was previously available only (if at all) through invasive and expensive exploratory biopsies. *Id.* ¶2. It offers healthcare professionals an unprecedented ability to monitor patients to detect rejection of a donated organ earlier, more safely, and more accurately than the current standard of care. *Id.*

Natera has taken improper advantage of CareDx’s pioneering work to develop a competing “me too” test, Prospera. *Id.* ¶3. Natera currently advertises and promotes its late entry to the market with false claims that Prospera is supposedly superior to CareDx’s AlloSure based on a head-to-head comparison. *Id.* Natera’s weak study fails to support any claims about its own product, let alone its false comparative claims, because it is plagued by severe shortcomings. As set forth in detail in the Complaint, the samples in the Natera Study were not representative of the transplant populations, Natera’s claims rely on a test set that includes samples that were excluded in the actual publication of the study, the Natera Study improperly mixes populations of both “for cause” biopsies and protocol biopsies, and the Natera Study does not comply with the industry-standard Banff Rules. *Id.* ¶¶27-38. Natera’s false claims are contained in promotional, product marketing, and investor materials and presentations that are being disseminated in connection with the introduction of Prospera.

IV. LEGAL STANDARDS

A. Legal Standard for Motion to Dismiss Under 12(b)(1) or 12(b)(6)

A motion to dismiss “for lack of statutory standing is effectively the same as a dismissal for failure to state a claim.” *Baldwin v. Univ. of Pittsburgh Med. Ctr.*, 636 F.3d 69, 73 (3d Cir. 2011) (internal citations omitted). A court must “accept as true plaintiffs’ material allegations, and construe the complaint in the light most favorable to them.” *Id.* at 73-74 (citing *Alston v. Countrywide Fin. Corp.*, 585 F.3d 753, 758 (3d Cir. 2009)). “The complaint must state enough facts to raise a reasonable expectation that discovery will reveal evidence of [each] necessary element” of a plaintiff’s claim. *Wilkerson v. New Media Tech. Charter Sch. Inc.* 522 F.3d 315, 321 (3d Cir. 2008) (internal quotations and citations omitted). “The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims.” *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997) (internal citations omitted).

V. ARGUMENT

A. CareDx Has Standing To Bring A False Advertising Claim Under The Lanham Act

CareDx has standing to bring a false advertising claim under Section 1125(a) of the Lanham Act against Natera—a direct competitor making false claims about the performance of CareDx’s product. To establish standing, a plaintiff must generally allege (1) an injury in fact; (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision. *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555 (1992)). The Supreme Court held that standing to sue under 15 U.S.C. §1125(a) extends to plaintiffs whose interests fall within the “zone of interests” protected by the Lanham Act and whose injuries are proximately caused by

defendant's violations of the statute. *Lexmark Intern., Inc. v. Static Control Components*, 572 U.S. 118, 129-133 (2014).

CareDx's claims fall well within the zone of interests for false advertising under Section 1125(a) of the Lanham Act. To be within the zone, a plaintiff must allege injury to a commercial interest in reputation or sales. *Lexmark*, 572 U.S. at 131-32. CareDx has a commercial interest in AlloSure and credibly alleges that Natera's false statements about AlloSure have caused harm to its reputation and business. D.I. 1 ¶6. This comfortably falls within the ambit of interests protected by the Lanham Act.

Natera focuses on the second prong of the test, wrongly asserting that CareDx failed to plead that Natera proximately caused its injuries. To support its argument, Natera improperly attempts to introduce extrinsic evidence, claiming it is entitled to do so because it is making a factual attack, rather than a facial attack. D.I. 9 at p. 8-9. Natera is wrong: A defendant can only bring a factual attack after filing an answer, so any attack mounted before the filing of an answer is, by definition, a facial attack on the pleadings. *See Frompovicz v. Niagara Bottling*, 313 F.Supp.3d 603, 608 (E.D. Pa. 2018) (citing *Mortensen v. First Fed. Sav. & Loan Ass'n*, 549 F.2d 884, 892 (3d Cir. 1977)). In evaluating a facial attack, a court can only consider the allegations of the complaint and the documents referenced therein and attached thereto. *Id.* (citing *Constitution Party of Pa. v. Aichele*, 757 F.3d 347, 358 (3d Cir. 2014)). Because Natera has not yet filed an answer, the Court should not consider any extrinsic evidence in ruling on its claim that CareDx lacks standing.

Regardless, Natera's claim that CareDx has no competitors is without merit despite being in bold and italic lettering. Even if the Court were to consider Natera's improper evidence, it does not change reality; Natera and CareDx are marketing the same type of product to the same

audience of consumers, and Natera is making false statements that its product is superior to CareDx's. D.I. 1 ¶27. Unlike the cases Natera cites,¹ the instant case is a "classic" Lanham Act false advertising case—one in which a competitor directly injures another by making false statements about its own goods, or its competitors' goods, to induce customers to select one product over the other. *Lexmark*, 572 U.S. at 137. There is no question that "classic" Lanham Act cases satisfy the proximate cause prong of the *Lexmark* standing test: the Supreme Court explained that "a defendant who seeks to promote his own interests by telling a known falsehood to or about the plaintiff or his product may be said to have proximately caused the plaintiff's harm." *Id.* at 138 (internal quotations and citations omitted). Courts in the Third Circuit have readily found proximate cause for purposes of standing under the Lanham Act where a plaintiff has sued a direct competitor. *See e.g., Warner-Lambert Co. v. Breathasure, Inc.*, 204 F.3d 87, 95-97 (3d Cir. 2000) (noting that the standing analysis is only required when the plaintiff's and defendant's products are not in direct competition); *G&W Laboratories, Inc. v. Laser Pharmaceuticals, LLC*, No. 3:17-cv-3974-BRM-DEA, 2018 WL 3031943 at *13 (D.N.J. June 19, 2018) (finding proximate cause in a classic Lanham Act false-advertising claim where plaintiff alleged that it was directly injured by false claims made by a direct competitor about the equivalency of their products); *Steer Machine Tool & Die Corp. v. SS Niles Bottle Stoppers*, 331 F. Supp. 3d 429, 432-34 (M.D. Pa. 2018) (finding plaintiff had satisfied the requirement of proximate causation where it alleged that a direct competitor's conduct had and would continue

¹ Like *Lexmark*, two of the cases cited by Natera do not involve direct competitors. *See Avalos v. IAC/Interactivecorp.*, No. 13-cv-8351, 2014 WL 5493242 (S.D.N.Y. Oct. 30, 2014) (finding no allegation of proximate cause where the defendant was not a direct competitor and the plaintiff had not alleged any harm to its commercial interests as a result of defendant's conduct); *I Love Omni, LLC v. Omnitrition Int'l*, 3:16-cv-2410-G, 2017 WL 3086035 (N.D. Tex. July 20, 2017) (finding no allegation of proximate cause where plaintiff had not even specified what product was in direct competition to defendant's product).

to injure its business reputation, loss of revenue, and profits); *Frompovicz*, 313 F.Supp.3d at 613 (denying motion to dismiss where plaintiff sufficiently alleged proximate cause as defendant was a direct competitor and misleadingly marketed its product through misleading statements about its own product, without making any direct comparisons to plaintiff's product). And unlike *Nespresso USA, Inc. v. Ethical Coffee Company SA*, where plaintiff failed to plead a connection between defendant's generalized statements about environmental impact and its alleged injury, in this case, there is no question that Natera is actively making head-to-head comparisons, falsely claiming that Prospera is superior to AlloSure. D.I. 1 ¶27; *Nespresso USA, Inc. v. Ethical Coffee Company SA*, No. 16-194-GMS, 2017 WL 3021066 (D. Del. July 14, 2017).

Moreover, Natera's claims that CareDx does not have standing because Prospera is not yet on the market are irrelevant as a matter of law because the Lanham Act explicitly authorizes suit by any plaintiff that believes that he or she is *likely* to be damaged by a defendants' false advertising. *See Lexmark*, 572 U.S. at 129. The Supreme Court has expressly found that the Lanham Act protects both past and future harm to plaintiffs. *Id.* at 131 (finding that Congress intended the Lanham Act to protect plaintiffs from "injuries to business reputation and present and *future* sales") (emphasis added). The injury here is not a distant possibility; rather, it is a present reality as Natera is unquestionably disseminating its false statements about CareDx's products to advertise its own product.

Natera's contention that CareDx must sit quietly without a remedy for months, watching Natera make unchecked false claims about CareDx's product until CareDx is able to point to a specific lost sale is wrong, as a matter of equity, law, procedure, and common sense. *See Breathasure, Inc.*, 204 F.3d at 95-97 (finding Lanham Act plaintiff need not present proof of actual loss, but need only show that it has a reasonable basis to believe that it is likely to suffer

injury). Here, CareDx has a reasonable basis to believe it will be harmed by Natera's misleading promotion of Prospera. Natera's press releases, public filings, marketing and promotional presentations, and other statements tout Prospera's superiority to AlloSure, and denigrate AlloSure, actively soliciting sales from current AlloSure customers in anticipation of Prospera's release on the market. D.I. 1 ¶¶42-50. Such statements directly threaten CareDx's present and future sales and are damaging to its reputation, regardless of whether Prospera is currently sold.

Moreover, when a defendant is marketing a developed product, courts have found that a plaintiff has standing under the Lanham Act even if the product is not yet on the market. For example, in *Par Sterile Products, LLC v. Fresenius Kabi USA LLC*, the court found that plaintiff had standing under 1125(a) of the Lanham Act where the defendant had a "concrete competing product" that was fully developed and ready for sale to compare with plaintiff's product. *Par Sterile Products, LLC v. Fresenius Kabi USA LLC*, No. 14 C 3349, 2015 WL 1263041 at *3 (N.D. Ill. Mar. 17, 2015). In *Par Sterile*, the allegation that plaintiff was likely to suffer as a result of defendant's misrepresentations about a competing drug prior to the drug's actual sale was sufficient to confer standing. *Id.* In the present case, CareDx has satisfied the standing requirements under the Lanham Act by alleging that Natera's false and misleading statements have directly harmed and will continue to harm CareDx.

B. CareDx Has Pled Facts Sufficient To Show That Natera's False And Deceptive Advertising Violates The Lanham Act

As the Third Circuit has emphasized, "Congress enacted section 43(a) of the Lanham Act to stop the kind of unfair competition that consists of lying about goods or services." *Castrol Inc. v. Pennzoil Co.*, 987 F.2d 939, 941 (3d Cir. 1993) (internal quotations and citations omitted). To state a cognizable Lanham Act claim for false advertising, a plaintiff must plead facts showing that defendant (1) has made false or misleading claims about its own or plaintiff's

product; (2) that there is actual deception or at least a tendency to deceive a substantial portion of the intended audience; (3) that the deception is material; (4) that the product has traveled in interstate commerce; and (5) that there is a likelihood of injury to plaintiff in terms of declining sales, loss of good will, etc. *Pernod Ricard USA, LLC v. Bacardi U.S.A., Inc.*, 653 F.3d 241, 248 (3d Cir. 2011) (citing *Breathasure, Inc.*, 204 F.3d at 91-92). If an advertisement is literally false, a plaintiff is excused from showing the second element. *Id.* (citing *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharmaceuticals Co.*, 290 F.3d 578, 586 (3d Cir. 2002)). Accepting the well-pled allegations of the Complaint as true, as courts are required to do when evaluating a motion to dismiss, *Baldwin*, 636 F.3d at 73, CareDx has indeed alleged a cognizable Lanham Act claim.

1. Natera's False and Deceptive Advertising

The Complaint alleges numerous facts showing that Natera's advertisements are false and misleading, so Natera's contention that "CareDx has not identified any statements by Natera that are 'false on their face'", D.I. 9 at p.11, is flat wrong. Indeed, among others, paragraphs 39-49 of the Complaint detail a variety of false claims, and CareDx specifically alleges that, "all claims that [Natera's] tests demonstrate anything about Prospera's performance compared to AlloSure's performance are literally false and entirely misleading." D.I. 1. ¶37. To the extent Natera disagrees with CareDx's allegations, that dispute will be resolved by a fact-finder based on evidence; a motion to dismiss is not the proper procedural vehicle to resolve the dispute over the veracity of CareDx's factual challenges. *Frompovicz*, 313 F.Supp.3d at 608 ("a defendant may mount a factual attack only after filing an answer") (citing *Mortensen*, 549 F.2d at 892). All that CareDx must do at this stage is to state a cognizable legal claim and this detailed recitation of false claims clearly does so, easily exceeding a bare recitation of the elements of the claim. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007).

Natera attempts to excuse its deceptive claims as some kind of “scientific disagreement.” D.I. 9. at p. 11. As the Fifth Circuit has explained, “Advertisements do not become immune from Lanham Act scrutiny simply because their claims are open to scientific or public debate. Otherwise, the Lanham Act would hardly ever be enforceable—‘many, if not most, products may be tied to public concerns with the environment, energy, economic policy, or individual health and safety.’” *Eastman Chemical Co. v. Plastipure, Inc.*, 775 F.3d 230, 236-7 (5th Cir. 2014) (quoting *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 563 n. 5 (1980)).

Natera’s contention that if its press releases and other false advertisements simply recited the results of its extremely flawed study, there would be no Lanham Act claim is dubious at best.² But the Court need not consider that issue. As the Complaint explains, Natera is not simply quoting from the publication of the Natera Study, but instead is making false claims that Prospera “compares favorably against competition” or “Outperforms Competition” See D.I. 1 ¶¶39-49. Those are not matters of scientific disagreement; they are demonstrably false comparative claims. The cases Natera relies upon have no relevance here. *ONY, Inc. v. Cornerstone Therapeutics, Inc.* involved promotional materials discussing the findings of a single study and plaintiff took issue with the statements made in the study itself. 720 F.3d 490, 496 (2d Cir. 2013). Here, CareDx does not challenge statements made *in* the publication of the Natera Study, which nowhere states that Prospera is better than AlloSure. See D.I. 1, Ex. 1.

² See *Eastman Chemical Co. v. Plastipure, Inc.*, 775 F.3d 230, 236 (5th Cir. 2014) (“This lawsuit is not about Dr. Bittner’s scientific paper. It is about statements made in commercial advertisements or promotions, not statements made in a peer-reviewed journal. ...It is about statements made without the necessary context presented by a full scientific study, such as a description of the data, the experimental methodology, the potential conflicts of interest, and the differences between raw data and the conclusions drawn by the researcher.”) (citations omitted).

Johnson & Johnson Vision Care, Inc. v. 1-800 Contacts, Inc., 299 F.3d 1242 (11th Cir. 2002), is also unavailing, as it involved a single head-to-head patient preference study that sought to determine which brand of contact lens test participants preferred as more comfortable, convenient and easier to handle. The claims at issue in *Johnson & Johnson* did not involve the sort of cross-study comparison at issue here, nor did plaintiff there “contest the reliability of the [patient preference survey].” *Id.* at 1249 n. 6. Here, of course, not only are the challenged claims not in the scientific paper, but CareDx does contest the reliability of the study.

The challenged advertising here is not merely faithful recitations of findings from a single scientific study as in *ONY* and *Johnson & Johnson*, but is instead a deceptive head-to-head comparison without the support of a head-to-head study. Natera makes a false comparison in promotional materials between two tests, each of which was designed to validate the performance of a single product. No such comparison is in the Natera Study itself, which is not a head-to-head study. D.I. 1, Ex. 1. Accordingly, unlike plaintiff in *ONY* who “sought to enjoin statements made within the academic literature and directed at the scientific community,” Natera is seeking “to enjoin statements made in commercial advertisements and directed at customers,” which are not exempt from the Lanham Act. *Eastman Chemical*, 775 F.3d at 236 (affirming entry of injunction enjoining scientific statements that were presented in a false and misleading manner in commercial advertising); *see also*, *Biolase, Inc. v. Fotona Proizvodnja Optoelektronskih Naprav D. D.*, Case No. SACV 14-0248 AG (ANx), 2014 WL 12577153, at *3 (C.D. Cal, Sept. 15, 2014) (denying motion to dismiss where study does not conclude that defendant’s products are superior and defendants failed to “show that the article supports such statements”).

Although there is no need to reach the issue on a motion to dismiss, Natera's arguments concerning CareDx's burden of proof on the merits misstate the legal standard. D.I. 9 at p. 11. It is generally true that a plaintiff has the burden to show that a challenged advertisement is false or misleading. But, where, as here, promotional materials implicitly or explicitly refer to tests or data establishing a product's superiority—an establishment claim—a plaintiff satisfies its burden by proving either that: (1) “the tests were not sufficiently reliable to permit a conclusion that the product is superior”; or (2) even though the tests are reliable, “[they] do not establish the proposition asserted by the defendant,” rendering the advertisement literally false. *Castrol, Inc. v. Quaker State Corp.*, 977 F.2d 57, 62-63 (2d Cir. 1992) (citing *McNeil-P.C.C., Inc. v. Bristol-Myers Squibb Co.*, 938 F.2d 1544, 1549 (2d Cir. 1991); *Procter & Gamble Co. v. Chesebrough-Pond's, Inc.*, 747 F.2d 114, 118 (2d Cir.1984)); *see also Schering-Plough Healthcare Prods., Inc. v. Neutrogena Corp.*, 702 F. Supp. 2d 266, 275 (D. Del. 2010).

Natera has not performed a study directly comparing Prospera and AlloSure and “it is a fundamental principle of clinical testing that one cannot infer efficacy comparisons between two products when, as here, those products have not been tested against one another in a well-controlled head-to-head clinical study.” *Zeneca, Inc. v. Eli Lilly & Co.*, No. 99 CIV. 1452 (JGK), 1999 U.S. Dist. LEXIS 10852, *100 (S.D.N.Y. July 15, 1999); *see also, Am. Home Prods. Corp. v. Johnson & Johnson*, 577 F.2d 160, 169 n. 19 (2d. Cir. 1978) (finding study failed to support claim of superiority because the two drugs were never directly compared by the same subjects); *Healthport Corp. v. Tanita Corp. of Am.*, 563 F. Supp. 2d 1169,1179 (D. Ore. 2008) (finding a statement that a body composition analyzer was “unsurpassed in accuracy and validity” to be literally false where studies relied upon did not compare the analyzer to similar products); *Thompson Medical Co., Inc. v. Ciba-Geigy Corp.*, 643 F. Supp. 1190, 1195 (S.D.N.Y.

1986) (enjoining Ciba from making false implied superiority claims “unless and until plaintiff has at least one adequate and well-controlled comparative clinical study which demonstrates such therapeutic advantage or superiority”). In the absence of a well-controlled comparative study that demonstrates superiority, Natera’s claims are false.

2. CareDx Need Not Identify Any Specific Individual Who Was Deceived

Without citation to caselaw, or presentation of persuasive logic, Natera contends that its deceitful advertisements are not material and did not impact purchasing decisions, supposedly because the Complaint does not identify a specific individual who was actually deceived. D.I. 9 at pp. 12-13. But that is not CareDx’s burden at the pleading stage. When—as here—a claim is literally false, a plaintiff is not required to prove actual deception because “actual deception or a tendency to deceive is presumed.” *Pernod Ricard*, 653 F.3d at 248. *See also, Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014); *Castrol*, 987 F.2d at 943.

Natera wrongly asserts that CareDx has failed to allege that Natera’s false advertisements influenced a purchasing decision, D.I. 9 at p. 13. CareDx alleges that Natera’s misrepresentations have influenced purchasing decisions by encouraging consumers to use Propsera instead of AlloSure, and **not** to use AlloSure, causing CareDx to lose sales and prospective business prospects. D.I. 1 ¶¶ 57-58.

Natera is also wrong in asserting that CareDx cannot allege that Natera’s false advertisements have influenced a purchasing decision as a matter of law because Natera has not yet made a sale. D.I. 9 at p. 13. A plaintiff may establish materiality by proving that “the defendants misrepresented an inherent quality or characteristic of the product.” *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litig.*, No. 14-MD-2542 (VSB), 2019 WL 1789789, at *34 (S.D.N.Y. Apr. 22, 2019) (internal quotations omitted). Here, the false

statements are clearly material, in that a statement that Prospera is superior because it purportedly detects AR with greater sensitivity or is more reliable, D.I. 1. ¶ 55, is likely to affect purchasing decisions. Moreover, the Lanham Act does not require plaintiffs to wait until they have actually been harmed; the statute itself expressly authorizes a party “who believes that he or she is or is likely to be damaged” to bring an action. 15 U.S.C. §1125(a)(1) (emphasis added). CareDx has alleged that: (1) CareDx and Natera are competitors who have both introduced genomic-based testing services and products; (2) Natera has undertaken significant marketing efforts for Prospera, including by making it available for use in clinical trials and marketing it to major clinical centers; and (3) CareDx is being harmed through loss of goodwill, reputation, profits and prospective business contracts. See D.I. 1 at ¶¶ 51-53. These allegations are sufficient to withstand a motion to dismiss.

3. CareDx’s Injuries Caused by Natera’s Deceptive Advertising

Natera again misunderstands the law when it contends that CareDx has not shown injury. CareDx alleges that Natera has made false statements about both its own and CareDx’s products, harming CareDx’s reputation and causing it to lose sales. D.I. 1 ¶¶ 51-53. As discussed above, this case presents what the Supreme Court has recognized as “paradigmatic direct injury” in “the classic Lanham Act false-advertising claim in which one competitor directly injures another by making false statements about his own goods or the competitor’s goods and thus inducing customers to switch.” *Lexmark*, 572 U.S. at 137-38 (internal quotations omitted).

The “likelihood of injury” requirement is satisfied where the plaintiff demonstrates a reasonable basis for believing that the deceptive advertising will cause injury in the future. *Novartis*, 290 F.3d at 595; *Breathasure*, 204 F.3d at 95-96 (noting that a reasonable basis for a believing that false advertising will cause injury generally equates with a reasonable showing of a likelihood of future harm under the Lanham Act); *Johnson & Johnson v. Carter-Wallace, Inc.*,

631 F.2d 186, 190 (2d Cir. 1980) (finding Lanham Act plaintiff not required to prove actual loss and specific evidence of causation to meet standing requirement). For all of these reasons, Natera's motion to dismiss the Lanham Act claim should be denied.

C. CareDx Has Stated A Cause of Action for Trade Disparagement

CareDx has stated a cause of action for trade disparagement under the Lanham Act. *See Parker v. Google, Inc.*, 242 Fed. App'x 833, 838-39 (3d Cir. 2007) (noting that the Lanham Act provides for a claim of trade disparagement). The Lanham Act provides:

any person who, on or in connection with any goods or services . . . uses in commerce any word, term, name, symbol, or device, . . . false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act. 15 U.S.C. § 1125(a)(1)(B).

The gravamen of CareDx's claim clearly meets the elements of the statute. Natera's representatives and agents made false and disparaging statements about AlloSure's nature, characteristics, and quality. D.I. 1. ¶¶62-66. Further, to bring a claim for trade disparagement under the Lanham Act, a plaintiff need only allege that defendant's actions may be considered commercial advertising or promotion under the Lanham Act, and that the defendant's misrepresentations are part of a campaign to penetrate the relevant market. *NXIVM Corp. v. Ross Institute*, 364 F.3d 471, 482 (2d Cir. 2004) (citing *Fashion Boutique of Short Hills, Inc. v. Fendi USA, Inc.*, 314 F.3d 48, 57 (2d Cir. 2002)). CareDx has explicitly detailed that Natera's commercial advertising for Prospera is an attempt to penetrate the market for cell-free DNA

kidney transplant surveillance diagnostic tests. See D.I. 1 ¶ 56. CareDx has sufficiently pled its claims for trade disparagement and should survive this motion to dismiss.³

The cases Natera cites are inapplicable to the present case. They are all from outside the Third Circuit and none involved pure product disparagement as compared to abuse of trademarks which is not at issue here. See *Freecycle Network, Inc. v. Oey*, 505 F.3d 898, 905 (9th Cir. 2007) (finding that plaintiff did not plead the elements of 1125(a) where it alleged no false statements); *Peter Brasseler Holdings, L.P. v. Brasseler GmbH & CO. KG, Kobra, Inc.*, No. 407CV25, 2017 WL 4481517 (S.D. Ga. 2007) (noting plaintiff only alleged claims of trademark infringement); *Most Worshipful National Grand Lodge, Free & Accepted Ancient Yorkrite Masons, Prince Hall Origin Nat'l Compact, U.S.A. v. United Grand Lodge GA AF & AFYM, Inc., et al.*, No. 1:17-CV-2582-TWT, 2018 WL 4828398, at *5 (N.D. Ga. 2018) (noting plaintiff only brought a disparagement claim under state law).

D. Natera Has Violated Delaware State Law

1. Natera Is Violating Delaware Common Law Unfair Competition Law

The Third Count of the Complaint properly alleges common law unfair competition. Natera's contention that there is no federal common law cause of action for unfair competition is simply irrelevant because Delaware courts do recognize the cause of action. See, e.g., *L. Casapulla & Sons v. Casapulla*, CIV. A. No. 10045, 1989 WL 40791 (Del. Ch. Apr. 20, 1989). In addition, the Complaint sufficiently alleges facts to state a claim for unfair competition, which require allegations that a plaintiff had "a reasonable expectancy of entering a valid business

³ Natera clearly has notice of CareDx's allegations under 15 U.S.C. §1125(a). D.I. 9 n. 6. See *Mayor and Council of Borough of Rockaway v. Klockner & Klockner*, 811 F. Supp. 1039 (D.N.J. 1993) (citing *Alexander v. Unification Church of America*, 634 F.2d 673, 678) (2d Cir.1980)) (finding that mislabeling a claim is not fatal to the count because Rule 8 of the federal rules merely requires a pleading to give defendant fair notice of claims asserted against it).

relationship, with which the defendant wrongfully interferes, and thereby defeats the plaintiff's legitimate expectancy and causes him harm.” *Agilent Techs., Inc. v. Kirkland*, C.A. No. 3512-VCS, 2009 WL 119865, at *5 (Del. Ch. Jan. 20, 2009) (internal citation and quotations omitted). Delaware courts have explained that “the true test is whether the defendant's acts are reasonably calculated to deceive the average buyer under the ordinary conditions prevailing in the particular trade.” *State ex rel. Brady v. Wellington Homes, Inc.*, No. 99C-09-168-JTV, 2003 WL 22048231, at *2 (Del. Super. Ct. Aug. 20, 2003) (quoting *Coca-Cola Co. v. Nehi Corp.*, 36 A.2d 156, 165 (Del. 1944)). Here, CareDx has alleged that it had a reasonable expectancy of entering into business relationships with patients and healthcare providers and Natera interfered with those relationships by making false and misleading statements to influence those patients and healthcare providers to use Natera's product instead of AlloSure, as well as to harm CareDx's reputation and business prospects in the marketplace. D.I. 1 ¶¶ 68-72. Natera's actions have caused harm by preventing CareDx from earning revenue and building goodwill in the marketplace. CareDx should be permitted to proceed with its common law unfair-competition claim.

2. Natera Is Violating the Delaware Unfair and Deceptive Trade Practices Act

CareDx has also pled a legally-cognizable claim under the Delaware Unfair or Deceptive Trade Practices Act (“UDTPA”). Natera's first contention—that the Complaint fails to identify which of the twelve subsections of the UDTPA Natera has violated—is simply wrong. D.I. 9 at p. 17. Paragraph 81 of the Complaint clearly states that Natera's false and misleading statements violate the UDTPA 6 Del. C. §§2531-36. D.I. 1 ¶ 81.

Natera's second argument—that paragraphs 74-81 of the Complaint offer no factual allegations showing Natera's violations of UDTPA—also fails because Count IV includes

paragraphs 73-81. D.I. 9 at p. 18; D.I. 1 ¶¶ 73-81. Paragraph 73 of CareDx’s UPDTA claim, which Natera omits, “incorporates by reference all the allegations set forth above as if fully set forth herein.” D.I. 1 ¶ 73. The factual allegations elsewhere in the Complaint detail how Natera’s false statements have deceived the healthcare industry and consumers and caused, and will continue to cause, harm to CareDx. *See, e.g.*, D.I. 1 ¶¶ 37-53. Therefore (and as discussed more fully above), the Complaint has properly alleged facts demonstrating that Natera’s false claims have injured CareDx’s business or trade interest.

Moreover, the Delaware Deceptive Trade Practices Act (“DTPA”), prohibits the “disparagement of the goods, services or business of another by false or misleading representations of fact, committed in the course of a business, vocation, or occupation or that generally creates the likelihood of confusion or misunderstanding.” *Hologic, Inc. v. Minerva Surgical Inc.*, No. 1:15-cv-1031, 2019 WL 1958020, at *7 (D. Del. May 2, 2019) (citing 6 Del. C. §§ 2532(a)(8) & (a)(12)) (internal quotations omitted). The DTPA has a lower burden of proof than the Lanham Act, since a complainant need not prove competition between the parties or actual confusion or misunderstanding. *Id.* CareDx’s allegations of trade disparagement under the Lanham Act, as discussed above, therefore also readily satisfy the elements necessary to allege a disparagement claim under the DTPA.

The Court need not reach Natera’s third argument—concerning jurisdiction over state law claims in the absence of federal claims—because, as previously discussed, the federal claims survive.

VI. CONCLUSION

For the foregoing reasons, Natera’s motion to dismiss should be denied. Even if the Court were inclined to grant Natera’s motion to dismiss, it should be without prejudice and with leave to amend, as it clearly would not be futile to amend the Complaint. *See Alston v. Parker*, 363

F.3d 229, 235 (3d Cir. 2004) (noting that “even when a plaintiff does not seek leave to amend, if a complaint would be vulnerable to 12(b)(6) dismissal, a District Court must permit a curative amendment, unless an amendment would be inequitable or futile”) (citing *Grayson v. Mayview State Hosp.*, 293 F.3d 108 (3d Cir. 2002)). This is particularly true because since CareDx filed its Complaint on April 10, Natera has continued to falsely advertise Prospera and to disparage CareDx’s AlloSure. For example, Natera’s website now devotes an entire section to these deceptive claims (<https://www.natera.com/prospera>), and Natera has continued to issue press releases containing the false and misleading claims. *See, e.g.,* <http://investor.natera.com/phoenix.zhtml?c=254055&p=irol-newsArticle&ID=2399290>. Earlier this month, from June 1-5, 2019, Natera marketed Prospera at the American Transplant Congress in Boston with claims that go even further than those cited in the Complaint.

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